Worcestershire Acute Hospitals NHS Trust

Medical management of mid-trimester miscarriage or termination of pregnancy using mifepristone/misoprostol

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Key Amendments

Date	Amendment	Approved by
14th December 2020	Documents extended for 3 years	Alex Blackwell
29th December 2023	Document extended for another 6 months whilst under review.	Alex Blackwell
20th August 2024	Document extended for another 6 months whilst under review.	Alex Blackwell

Introduction

This guideline has been written to guide the medical management of mid-trimester 9^{+0} – 20^{+0} weeks gestation) miscarriage or medical termination of pregnancy. The use of mifepristone and misoprostol for these clinical indications is thought to be less traumatic for the woman as well as being cost effective and evidence based.

Cautions:

- Asthma
- Chronic obstructive pulmonary disease
- Cardiovascular disease or risk factors
- Prosthetic heart valve or history of infective endocarditis (prophylaxis recommended)
- Haemorrhagic disorders and anti-coagulation therapy
- Adrenal suppression (may require corticosteroid)
- Breast-feeding

Contra-indications:

- Uncontrolled severe asthma
- Chronic adrenal failure
- Not recommended in chronic hepatic or renal impairment
- Ectopic pregnancy

Worcestershire Royal Hospital: Arrange admission to Lavender Gynaecology.

Alexandra Hospital: Women with pregnancies of gestations </= 15+6, arrange admission to the gynaecology ward. For women with gestations >/= 16+0, arrange admission to delivery suite.

The patient will be referred with the appropriate medical notes and investigation results, via: -

- Early Pregnancy Assessment Unit (EPAU)
- Ultra Sound Scan Department (USS)
- Antenatal Clinic (ANC)
- Accident and Emergency (A&E) department

1. Referral via EPAU, USS or ANC

Patient is seen by department staff and medical staff who will:

(i) Explain the procedure, including the fact that this is an unlicensed indication for misoprostol and answer any questions that patient/relatives may have.

(ii) Provide support and counselling as required, supported by relevant information leaflets and support group contact details.

(iii) Obtain informed consent, complete consent form (including information on the unlicensed use of misoprostol) and get woman to sign.

- For termination of pregnancy: Consent form to state "**Termination of Pregnancy and induction of labour with mifepristone and prostaglandins. +/- Evacuation of retained products of conception."**
- For miscarriage: Consent form to state "**Induction labour by prostaglandins +/- Evacuation of retained products of conception."**

(iv) Arrange for blue termination (HSA1 may be blue or white) form to be completed where there is a live foetus. This must be completed and signed by two Doctors in accordance with the 1967 Abortion Act. Commence form HSA4 (Yellow form and should be completed at delivery and returned within 14 days). Form to be completed by the doctor performing the termination.

(v) Complete and sign the white form for examination of foetal tissue.

(vi) Complete medical clerking.

(vii) Worcestershire Royal Hospital: Arrange admission to side room

2. Prescribe Regime for Administration
Complete drug chart.

(i) **Mifepristone 200mg only for patients undergoing termination of pregnancy and miscarriage >16 weeks' gestation** (to be given at onset of treatment). All patients undergoing termination of pregnancy require mifepristone irrespective of gestational age. Mifepristone is only give in cases of miscarriage >16 weeks.

Observe patients for 30 minutes and arrange admission 36 to 48 hours later for course of misoprostol as below.

(ii) Misoprostol 800 micrograms per vagina (4x 200microgram tablets).

then:

(iii) Misoprostol 400 micrograms (2 x 200 microgram tablets) orally every 3 hours following PV dose until total of 5 doses in 24 hours have been administered (inclusive of the PV dose).

(iv) Prescribe analgesia (NSAIDS to be avoided). Paracetamol 1g QDS, co-dydramol 2 tablets QDS as an alternative. Pethidine 50-100mg IM 4 hourly should also be prescribed.

(v) Ensure patient has access to inhaled analgesia (Entonox) and, if required, epidural analgesia should be considered.

3. Administration of Oral Mifepristone is only required for women undergoing termination if pregnancy and miscarriage >16 weeks' gestation. Women under 16 weeks diagnosed with miscarriage can proceed directly to misoprostol treatment

NB: A stock of mifepristone is kept on the ward in the Controlled Drug cupboard. A record is kept in the Controlled Drug register of any stock received on the ward and any doses dispensed to patients. Further supplies of mifepristone should be ordered from pharmacy using the Controlled Drug requisition book.

Misoprostol should be available in GAU (it does not need to go in the CD cupboard or be recorded in the CD register). Further supplies can be obtained from the pharmacy using the usual requisition book.

(i) Administer oral mifepristone 200mg as per protocol. Patient should be asked to remain on the ward for 30 minutes to be monitored for any vomiting. If she is well after 30 minutes she can be allowed to go home with a full explanation of procedure, what symptoms to expect i.e. bleeding and abdominal pain together with a contact number for the ward which she can ring if she has any concerns. The patient should be advised that she may take mild paracetamol based analgesia (TTOs to be provided) but to avoid NSAIDS.

(ii) Record label number of drugs in patient's notes and sign, date and time this entry.

4. Ensure a bed is blocked on the ward so the patient can return at any time.

5. Instruct patient to return to the ward 36 – 48 hours later to continue the procedure, usually at 0900 hrs.

6. On re-admission to the ward:

- Undertake baseline observations recording temperature and BP. Presence of any bleeding or abdominal pain to be discussed with patient and documented. ID wristband and allergy band applied.
- Site IV access and take bloods for FBC and Group and Save if this has not already been taken.
- Ensure patient understands the procedure and check consent form is signed.

7. Administration of Vaginal Misoprostol

(i) Administer misoprostol 800 micrograms PV (tablets moisten prior to administration) into posterior fornix. (This can be a nurse-led procedure see Appendix 1).

(ii) Advise the patient to rest on bed for ½ hour following insertion of tablets.

(iii) Commence 2 hourly observations and observe for bleeding and abdominal pain. Document in nursing notes as appropriate.

(iv) The patient may have fluids and light diet.

8. Commence regime of misoprostol 400 micrograms 3 hourly (orally) until 5 doses have been given (inclusive of PV dose).

- Have a delivery pack ready for delivery of the foetus.
- Continue until foetus is delivered. Cord should be clamped and cut.

<u>Pain relief during the procedure</u>

Almost all women will experience some abdominal discomfort during medical miscarriage or termination. The amount of pain experienced varies greatly from woman to woman but has been found to be higher in women of younger age, longer gestation, those with longer induction-to-expulsion of pregnancy interval and with increased number of misoprostol . Analgesic requirements have been shown to be less in older, parous women and those at shorter gestations.

All women having a termination of pregnancy should be offered adequate analgesia. Several studies have shown that the use of NSAIDs does not interfere with the action of misoprostol and/or mifepristone on inducing cervical ripening, uterine contractility or the time to abortion and expulsion of the products of conception.

The pain associated with this procedure is best managed by multimodal analgesic combinations due to the variability of the presentation.

The risk/ benefit ratio of using NSAIDS should be considered in patients with history of asthma, peptic ulcer disease and in renal insufficiency.

Before procedure

- PCA morphine connected to patient IV cannula before procedure
- IV paracetamol 1gm 6hourly
- Regular Ibuprofen 4oomg PO 8hourly
- IV Ondansetron 4mg PRN
- IM Cyclizine 50mg 8 hourly PRN

All Women should have baseline observations (SpO2, BP, HR, Resp. rate, Pain score and sedation score) documented before commencement of a PCA and half hourly for the first two hours, hourly for the next 4hours and two hourly thereafter.
Oxygen saturations and respiratory rate should be monitored continuously for the first 30minutes after the PCA is commenced.
Women who are not able to have any or all of the above regime (e.g. morphine allergy) should be discussed with the anaesthetic team of the day.

Post procedure (After expulsion of products of conception and placenta)

- Consider stopping PCA if comfortable
- Regular iv/po Paracetamol 1gm 6 hourly or NSAIDS if necessary

9. IM Syntometrine 1 ampoule (1ml) administered at delivery, as prescribed.

- Consider gentle cord traction or requesting patient to push which can assist in the delivery of the placenta.

- In event that the placenta is not delivered within 45 minutes of the administration of the Syntometrine, assessment by medical staff is required. IV fluids may be commenced. Patient should be nil by mouth. Bleeding and observations monitored. Book theatre for manual evacuation of retained products of conception – book main / CEPOD theatre. Explain the procedure and arrange for consent form to be signed or check that this has been incorporated in the original consent form.

The procedure should be performed by either the gynaecology senior middle grade or gynaecology consultant.

10. In the event of products of conception (POC) not being passed prior to the 5th dose of misoprostol then a PV examination should be performed by the senior middle grade / Gynae Consultant to ensure that POC are not in the vagina and to assess the cervix.

The on-call consultant should then be contacted for further management decision of either:

- Allow patient to rest for 12 hours following the last administered dose of misoprostol then recommence the misoprostol regime (consider intravenous fluid administration overnight and ensure the patient is aware that products of conception may be passed during the rest period) **OR**

- Commence administration of intravenous oxytocin (Syntocinon) 15iu in 500mls of 0.9% sodium chloride at 64mls an hour for a maximum of 6 hours.

11. When POC are completely delivered patient may then have diet and fluids and needs to stay for a minimum of 2 hours post-delivery or 4 hours post opiate analgesia.

12. Management of foetal tissue as per Trust protocol:
- Foetal disposal to be completed according to Trust protocol.
- Photographs/hand and footprints to be taken as per policy.

13. Check Rhesus status. Anti-D to be given as per Trust protocol.

14. Observations should be as clinically indicated but these should be at least 4 hourly with particular reference to temperature and nurses should be alerted to any signs of infection.

15. Prior to discharge the GP letter should be written. Any antenatal appointment should be cancelled. Follow up to be discussed with the patient and she should have the opportunity to discuss any concerns.

Following the patient being discharged from hospital it is the nurses' responsibility to ensure that: -
- Any planned USS and antenatal appointments are cancelled.
- Miscarriage notification form is completed.
- The patient's G.P and midwife are notified by telephone.
- Complete CESDI (Rapid Report Form) and forward to Clinical Midwife Specialist, Lavender Postnatal, WRH.
- Arrange consultant follow-up appointment if appropriate
- The SHO completes a comprehensive discharge summary for the G.P.

16. With MTOP in latter stages of the mid-trimester the patient should be told about the potential of the occurrence of lactation and advice given about managing this.

17. Patients should be advised re:(If relevant)

Investigations of foetus/placenta – written consent obtained
Disposal of products - ?funeral arrangements
Bereavement office contacted.
Memorial book.
Photographs taken and documented.

Footprints/Handprints.
Miscarriage support groups.

18. If appropriate refer to bereavement issues guideline (WAHT-OBS-061) re further investigations.

REFERENCES

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